

## REMARKS

Claims 12-14, 17, 20, 22, 23 and new claims 61-67 are pending in this application.

Claims 12, 20 and 23 have been amended to use the term “administering” in response to the 35 USC §112 rejection.

All of the pending claims were rejected as being anticipated by, or alternatively, obvious over “Elixir of Elderberry”, “Sambucal Black Elderberry”, Keville, Brown, Hirschhorn or Tanaka et al. Applicants respectfully traverse. None of the cited references, either alone or in combination teach the use of an extract from an anthocyanin-containing plant, such as elderberry, that is substantially free of anthocyanidins and which provides greater cyclooxygenase 2 (COX-2) inhibitory activity than cyclooxygenase 1 (COX-1) inhibitory activity, as provided in Claim 12. The present invention is directed to methods for reducing pain and its symptoms by selectively inhibiting the COX2 enzyme. As taught by applicants on page 30, lines 18 – 33, natural products, such as elderberry extracts may contain both non-active (glycosidic form with sugar) and active (aglycon form, anthocyanidin) forms each having different mechanisms of absorption, metabolism and transportation. With respect to the non-active form, it can be absorbed or passed through the GI tract without inhibiting the COX-1 enzyme in the GI tract. After its absorption in the GI tract, where the sugar moiety is cleaved, it is transported to the site where the COX2 enzyme is inhibited at a greater level than the COX1 enzyme. As claimed and taught by applicants on page 44, lines 18-25, an extract that is substantially free of active form, anthocyanidins, will be effective to reduce or alleviate pain.

With respect to claim 20, all of the cited references fail to teach or suggest the use of an extract that that is substantially free of anthocyanidins and which is provided in a dosage form that provides about 70 mg of anthocyanins. As shown by applicants in Example 7 of the present

application, a dosage of about 70 mg was most effective in reducing pain categorized as arthritis, dysmenorrhea, headache, joint pain, muscular pain, osteoarthritis. With respect to claim 23, the cited references do not teach or suggest the use of an extract that that is substantially free of anthocyanidins and includes an extract that contains a mixture of cyanidin-3-glucoside, cyanidin-3,5-diglucoside, cyanidin-3-sambubioside, and cyanidin-3-sambubioside-5-glucoside, and where that extract comprises at least 90% by weight of the total extract used to reduce pain. As noted in Table 11 and Example 7, a dietary supplement that contained 94 % by weight of elderberry extract as compared to the total anthocyanins provided in the extract (32 mg elderberry /34.2 mg total = 94%) was effective to reduce pain.

Because all of these references fail to teach or suggest these specific combinations of extracts, they can not anticipate or make obvious the invention.

This response is being submitted with a two month extension of time. In the event that further fees are due, the USPTO is authorized to charge Deposit Account No. 01-1793. Please contact the undersigned attorney at (616) 787-6360 to resolve any remaining issues.

Dated: December 30, 2003

Respectfully submitted,

By: 

Lynn Schwenning  
ALTICOR INC.  
Registration No. 37,233  
7575 Fulton Street East  
Ada, Michigan 49355  
(616) 787-6360  
(616) 787-9027 (fax)